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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,379	02/11/2000	Brian Mark Thomson	P06597USO/MP	2243

881 7590 03/26/2002

LARSON & TAYLOR, PLC  
1199 NORTH FAIRFAX STREET  
SUITE 900  
ALEXANDRIA, VA 22314

EXAMINER
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OZGA, BRETT T

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/26/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/446,379

Applicant(s)

THOMSON ET AL.

Examiner

Brett T Ozga

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8,11,12 and 14-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8,11,12 and 14-19 is/are rejected.
- 7) ☒ Claim(s) 2 and 6 is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 20) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

Applicant's amendment has been received and entered.

Claims 1,2,4-6,8,11,12 and 14-19 are pending.

#### ***Claim Objections***

Claims 2 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,4-6,8,11,12 and 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For example, in claim 1, line 3, applicant states that the cell anchoring layer comprises one of (i) various polyanions and (ii) a polypeptide. It is unclear whether applicant intends to choose one from each of groups (i) and (ii), making two total or just to choose one period. Rephrasing the claim with proper Markush language is recommended.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4,5,8,11,12 and 14-19 are rejected under 35 USC 103(a) as being unpatentable over Purchio et al. in view of Varani et al. (Cytotechnology, 1993, Vol. 13, No.2, pp. 89-98)

The broadest reasonable interpretation of the recitation in claim 1 is that one could choose just one of either the polypeptide or polyanions comprising the cell anchoring layer. In view of this interpretation, the rejection follows.

The instant application claims a wound dressing comprising a carrier layer (polymeric material) having a wound-facing surface, said surface being non-adherent to anchorage-dependent cells and having disposed thereon a biodegradable cell anchoring layer containing fibroblasts. Dependent claims further limit by adding a material adherent to anchorage-dependent cells. It also claims a method of treating a skin trauma site on a mammalian patient comprising the step of applying to a patient a wound dressing.

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Purchio et al. teach a wound dressing comprising a carrier layer with a surface being non-adherent to anchorage dependent cells. Bound to this carrier layer is an effective cell attachment-enhancing amount of an H3 protein, which contains the carboxy-terminal RGD sequence well known to promote cell attachment to a surface bearing the peptide. (See col.1, line 61.) They also teach an effective cell attachment-enhancing amount of H3 protein prior to contacting the support with the cells. (See col.2, lines 25-7.) Suitable carrier materials taught by Purchio et al. include polytetrafluoroethylene, nitrocellulose and cellulose. (See col.2, lines 33-7.) They also teach a shaped article comprising a solid support, H3 protein coated onto the supports and cells adhering to the H3-coated solid support (preferably, a three dimensional scaffold which may be either a sheet or mesh.)(See col. 2, lines 62-6) They also teach a method for accelerating wound healing comprising applying the solid support to the wound. Cells such as fibroblasts, epithelial cells and keratinocytes are attached to the carrier on the H3 treated surface. (See col. 3, lines 4-5).

Purchio does not specifically teach the cell attachment layer being polylysine. However, Varani et al. discloses polylysine in conjunction with RGD as a useful replacement for materials that were currently used as polystyrene microcarrier surfaces. (See abstract.) Also, using other supports and coating would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made in view of the many options given in the disclosure. Purchio et al. teach that there were currently no simple, effective methods for stimulating cell spreading and adhesion at wound sites to promote rapid wound healing.

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Thus, there is a need for substances able to promote attachment and spreading of cells, particularly fibroblasts, to facilitate this important process. (See col. 2, lines 13-19)

Polylysine is a conventional cell attachment promoting substance as taught by Varani et al. and given the motivation expressed above by Purchio, the selection of an alternative cell attachment layer would have been obvious to one of ordinary skill in the art at the time the invention was made. Further, the disclosure of multiple diverse choices as a carrier composition would render the selection of any of the claimed carriers not specifically recited in the patent obvious to one of ordinary skill in the art. Finally, the selection of allogenic and particularly, autologous, cells for use in the composition is clearly within the skill of the practitioner since the consequences of rejection are well known and one of ordinary skill in the art would be motivated to use autologous cells if available, and if not, would select allogenic cells in the alternative in order to obviate any issues of xenogenic rejection.

Applicant's arguments are moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers

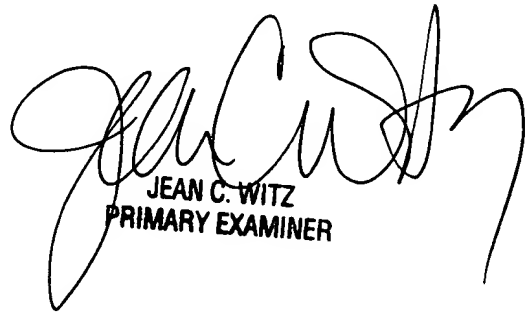
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for the organization where this application or proceeding is assigned are 7033084242

for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.

BTO  
March 22, 2002



JEAN C. WITZ  
PRIMARY EXAMINER